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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,328	11/19/2001	Avi J. Ashkenazi	P2730P1C54	9930

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EXAMINER	
KEMMERER, ELIZABETH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,328	ASHKENAZI ET AL.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *119-126,129-131 and 135-142* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *119-126 and 135-142* is/are rejected.

7)☒ Claim(s) *129-131* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment of 14 June 2004 has been entered in full. Claims 1-118, 127, 128 and 132-134 are canceled. Claims 119-126, 129-131 and 135-142 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the disclosure regarding improper use of hyperlinks as set forth at p. 2 of the previous Office Action (mailed 15 March 2004) is *withdrawn* in view of the amendment (received 14 June 2004).

The rejection of claims 119-124, 127, 128 and 132-138 under 35 U.S.C. § 112, second paragraph, as set forth at pp. 7-8 of the previous Office Action (mailed 15 March 2004) is *withdrawn* in view of the canceled and amended claims (amendment of 14 June 2004).

The rejection of claims 132-134 under 35 U.S.C. § 102(b) as set forth at p. 8 of the previous Office Action (mailed 15 March 2004) is *withdrawn* in view of the canceled claims (amendment of 14 June 2004).

35 U.S.C. § 112, First Paragraph

Claims 119-126 and 135-142 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acids, vectors and host cells comprising an isolated nucleic acid comprising the full-length coding sequence of the nucleic acid sequence shown in Figure 134 (SEQ ID NO: 206) or the full-length coding sequence of the cDNA deposited under ATCC accession number 209951, does not reasonably provide enablement for any variants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pp. 3-5 of the previous Office Action (mailed 15 march 2004).

Applicant's arguments (pp. 10-11, amendment received 14 June 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the amendment to the claims adding a functional limitation, "wherein the nucleic acid encoding said polypeptide is amplified in lung and colon tumors," obviates the rejection. Applicant disagrees with the examiner's conclusion that increases in gene copy number do not reliably correlate with increased gene expression or polypeptide expression. Applicant urges that increased gene expression and increased polypeptide expression have no bearing on the instant claims, since the claims are directed to nucleic acids that are amplified in tumors, not polypeptides or other gene expression products. Hence, Applicant contends that the Pennica, Konopka and Haynes references relied upon in the rejection is improper. Applicant argues that

the instant disclosure would know exactly what nucleic acid variants the instant claims encompass and would know how to make and use the same for diagnosis of lung and colon cancer. This has been fully considered but is not found to be persuasive. At the broadest, the claims read on nucleic acids that are at least 80% identical to he nucleic acid sequence of SEQ ID NO: 206, or nucleic acids that are at least 85% identical to any degenerate variant nucleic acid encoding the polypeptide of SEQ ID NO: 207. These claims encompass a large number of variants. The specification only shows that the full-length coding sequence of SEQ ID NO: 206 constitutes a specific probe to detect certain lung and colon tumors. The specification provides no guidance or working examples regarding what variants of the full-length coding sequence of SEQ ID NO: 206 would retain probe specificity. Determining which variants within the scope of the claims would retain probe specificity would require a great amount of experimentation. The state of the art is such that the skilled artisan would not make variants of a specific probe to make a different probe for the same target, knowing that making a probe that is less than 100% identical to its target would reduce probe specificity. The effects of sequence alteration on probe specificity are unpredictable. Based on these considerations, it is concluded that undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope. One must also consider whether or not the encoded polypeptide could be used as a cancer diagnostic. If the gene amplification could be tied to over-expression of the encoded polypeptide, then the claimed variants could be used to make the polypeptide which could then be used to make diagnostic, labeled antibodies. However, as

discussed in the previous Office Action, it cannot be assumed that gene amplification results in over-expression of mRNA or polypeptide. See Pennica, Konopka and Haynes, cited in the previous Office Action. Therefore, the specification also does not teach the skilled artisan how to use the claimed variants to make polypeptide-based diagnostics without undue experimentation. For all of these reasons, the rejection is maintained.

Claims 119-126 and 135-142 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pp. 5-7 of the previous Office Action (mailed 15 March 2004).

Applicant's arguments (pp. 11-13, amendment received 14 June 2004) have been fully considered but are not found to be persuasive for the following reasons.

Applicant reviews the legal standard for written description, with which the examiner takes no issue. Applicant urges that they were in possession of the invention as of the filing date considering the level of knowledge and skill in the art as well as the teaching provided by the specification. Applicant urges that the inventor is not required to describe every detail of the invention. Applicant concludes that the skilled artisan would have recognized that the inventors were in possession of the claimed genus of nucleic acid molecules which are both structurally and functionally defined. This has

been fully considered but is not found to be persuasive. The specification provides a single species having the structural and functional limitations set forth in the claims. The single species does not a representative number of species to support the claims. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Objections

Claims 129-131 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent for including all of the limitations of the base claim and any intervening claim. The basis for this objection was set fort at p. 9 of the previous Office Action (mailed 15 March 2004).

Applicant argues (pp. 13-14, amendment of 14 June 2004) that the objection is overcome since claim 124 is believed to be allowable. This has been fully considered but is not found to be persuasive because claim 124 is not allowable over 35 U.S.C. § 112, first paragraph, as discussed above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Thursday, 7:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER